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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,374	10/15/2003	James M. Chen	263.PC	9279

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EXAMINER	
HUANG, EVELYN MEI	
ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,374	CHEN ET AL.	
	Examiner	Art Unit	
	Evelyn Huang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63 and 68* is/are pending in the application.

4a) Of the above claim(s) *3,4,7,10,11,24,46 and 52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 5, 6, 8, 9, 12-23, 25-45, 47-51, 53-63, 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-63, 68 are pending. Claims 64-67, 69-79 have been canceled according to the amendment filed on 9-30-2004.

Election/Restrictions

2. In response to the restriction requirement mailed on 6-24-2004, Applicant has elected Group 1, Claims 1-63, and 68 for examination. The individual species of compound 149 of Claim 48, page 393 is elected.

Further restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 22, 23, 25, 48, 51, 53, and claims 1, 2, 5, 6, 8, 9, 12-21, 26-44, 47, 49, 50, 54-63, 68 in part, drawn to a compound of formula Ia, wherein Y--Z is $C(R^2)=C(R^3)$, $A^1=C(R^2)_2$, $A^2=C(R^2)=C(R^3)$, $Q=CR^4$, classified in class 546, subclass 84, and the composition thereof.

II. Claims 1, 3, 5, 6, 8, 9, 12-21, 26-44, 49, 50, 54-63, 68 in part, drawn to a compound of formula Ib, wherein Y--Z is $C(R^2)=C(R^3)$, $A^1 = C(R^2)_2 - C(R^3)_2$, $A^2=C(R^2)=C(R^3)$, $Q=CR^4$, classified in class 546, subclass 81, and the composition thereof.

III. Claims 1, 4, 5, 6, 8, 9, 12-21, 26-44, 49, 50, 54-63, 68 in part, drawn to a compound of formula Ic, wherein Y--Z is $C(R^2)=C(R^3)$, $A^1=C(R^2)_2- C(R^3)_2 - C(R^3)_2$, $A^2=C(R^2)=C(R^3)$, $Q=CR^4$, classified in class 540, subclass 522, and the composition thereof.

IV. Claim 24 and claims 1, 4, 5, 6, 8, 9, 12-20, 26-44, 49, 50, 54-63, 68 in part, drawn to a compound of formula Id, wherein Y--Z is $C(R^2)=C(R^3)$, $A^1 = C(R^2)_2 -$

C(O)NR, A^2 =C(R^2)=C(R^3), Q=CR^4, classified in class 546, subclass 81, and the composition thereof.

V. Claim 46 and claims 1, 3, 5, 6, 8, 11-20, 26-44, 49, 52, 54-63, 68 in part, drawn to a compound wherein Y--Z is N-C(=X), A^1 = C(O) C(R^3)$_2$, A^2 =C(R^2)=C(R^3), Q=CR^4, classified in class 544, subclass 345, and the composition thereof.

VI. Claims 7, 10, and claims 1-6, 8-20, 26-44, 47, 49, 50, 52, 54-63, 68 in part, drawn to a compound not included in Groups I-V, class and subclass various dependent on the species elected, and the composition thereof. If this group were elected, a species election is required. Further restriction is also required.

The inventions are distinct, each from the other because of the following reasons:

The compounds of Groups I to VI are structurally, chemically and patentably distinct. They have acquired a separate status in the art as shown by their different classification. A reference anticipating one group of invention would not render obvious the other groups of inventions. The search is not co-extensive and is burdensome. Since the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

2. Applicant has elected compound 149 of Claim 48 as the species, which falls within Group I, Claims 22, 23, 25, 48, 51, 53, and claims 1, 2, 5, 6, 8, 9, 12-21, 26-44, 47, 49, 50, 54-63, 68 in part. Claims of Groups II-VI are withdrawn from further consideration as being drawn to the non-elected inventions.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, 6, 8, 9, 12-21, 26-44, 49, 50, 54-63, 68, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1,

- In the definitions of Ar, R^1-R^4, R, R^{X2}, 'C2-C20 heteroaryl' is open-ended when the number and kinds of heteroatoms are not recited.
- Definition of R^{X2}, the meaning of 'a prodrug, a pharmaceutically acceptable prodrug' is unclear. Does applicant imply that within the prodrug, some are not pharmaceutically acceptable? Furthermore, R^{X2} is a substituent, so it is unclear how it can be a prodrug rather than a prodrug moiety.

b. Claim 13, the term 'comprising' in 'a compound of claim 1 comprising' is open-ended and is therefore indefinite.

c. Claim 21, the term 'comprising' in 'a compound of claim 9 comprising' is open-ended and is therefore indefinite.

d. Claim 27, the term 'comprises' in 'a compound of claim 26 wherein at least one R comprises' is open-ended and is therefore indefinite.

e. Claim 31, the term 'comprises' in 'a compound of claim 1 wherein at least one R1-R4 comprises' is open-ended and is therefore indefinite.

f. Claim 35, the term 'comprising' in 'a compound of claim 1 comprising ' is open-ended and is therefore indefinite.

g. Claim 36, the term 'comprising' in 'a compound of claim 1 comprising ' is open-ended and is therefore indefinite.

h. Claim 54, the term 'comprising' in 'a compound of claim 1 comprising ' is open-ended and is therefore indefinite.

i. Claims 35, the prodrug structures, and the variables R5-R7 have no antecedent basis in the base claim 1.

j. Claim 36, the phosphonate or prodrug moiety, the variables Y1, Y2, M2, M12a, M12b, Rx, Ry, M1a, M1c, M1d, M12c have no antecedent basis in the base claim 1.

k. Claim 38, the variable Y2b has no antecedent basis in base claim 37.

l. Claim 39, the variables Y2c, W5 have no antecedent basis in the base claim 37.

m. Claim 41, W5 has no antecedent basis in base claim 37.

n. Claim 42, M12d, Y2b, R1, R2, M12d have no antecedent basis in base claim 41.

o. The term "improved" in claim 54 is a relative term which renders the claim indefinite. The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The rejection is applicable to claims dependent on the above claims.

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 21-23, 25, 45, 47-51, 53 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 21-23, 25, 45, 47-51, 53 of copending Application No. 10/687373. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5, 6, 8, 9, 12-20, 26-44, 54-63, 68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-63, 68 of copending Application No. 10/687373. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of copending claims 21-23, 25, 45, 47-51, 53, the process of making and the composition thereof, are encompassed by the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

6. The compounds of Murray et al. (Synthesis 1996, 10:1180-1181) have been excluded from the claims. Motivation to modify Murray's compound to arrive at the instant invention is lacking.

The acetylcholine enhancer compound of Chalmers (6218402) is a pyrrolo[3,4-b]quinoline- 1-one, whereas the instant is a pyrrolo[3,4g]quinolin-8-one. Motivation to modify Chalmers' compound to arrive at the instant invention is lacking.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Evelyn Huang
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Art Unit 1625